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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,715	05/14/2007	Sergey I. Chernysh	SPSUP0100WOUS	4071
23908 7590 03/10/2010 RENNER OTTO BOISSELLE & SKLAR, LLP 1621 EUCLID AVENUE NINETEENTH FLOOR CLEVELAND, OH 44115				
EXAMINER GUSLOW, ANNE				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
03/10/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/585,715

**Applicant(s)**

CHERNYSH ET AL.

**Examiner**

Anne M. Gussow

**Art Unit**

1643

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,7-10,14,15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 7-10 is/are rejected.
- 7) ☒ Claim(s) 14,15 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1 and 10 have been amended.

Claims 2-4, 6, 11-13, 16, and 21-26 have been cancelled.

Claims 18-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 17, 2008.

2. Claims 1, 5, 7-10, 14, 15, and 17 are under examination.
3. The following office action contains NEW GROUNDS of Rejection.

### ***Objections Withdrawn***

4. The objection to the specification is withdrawn in view of applicant's amendment to the specification.

### ***Rejections Withdrawn***

5. The rejection of claims 1, 2, 6-17, and 22-26 under 35 U.S.C. 102(b) as being anticipated by Fishleigh, et al. is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained/ NEW GROUNDS of Rejection***

***Claim Objections***

6. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 2 is drawn to a broader group of peptides than the peptide in claim 1.

7. Claim 1 is objected to because of the following informalities: the claim contains a peptide sequence which is not identified by SEQ ID No. The sequence appears to be SEQ ID No. 1. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. The rejection of claims 1, 5, and 7-10 under 35 U.S.C. 101 as being directed to non-statutory subject matter is maintained.

Applicant's arguments filed January 7, 2010 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that claim 1 has been amended to recite a peptide having the general structural formula: His-Gly-Val-Ser-Gly-Trp-Gly-Gln-His-Gly-Thr-His-Gly. The peptide of SEQ ID No. 1 (allostatin-1) of the claimed invention is an artificial sequence, as it is mentioned in the List of

Sequences, and is significantly different from the structure of any known natural or synthetic peptides represented in Swissprot or other available protein and peptide data bases. It was obtained by the chemical synthesis process described on pages 3 and 6 of the specification. Furthermore, the biological activity of the peptide SEQ ID NO. 1 (allostatin-1) differs from the activity of structurally similar naturally occurring peptide alloferon 1 (SEQ ID No. 12) in the way that makes allostatin-1 more prospective for clinical as is demonstrated in the Example 2 of the specification (see response pages 5-6).

In response to this argument, the peptide sequence of SEQ ID No. 1 does not contain any non-naturally occurring amino acids. The identity of the peptide as an artificial sequence in the sequence listing does not prevent the sequence from being naturally expressed by a cell of as yet unknown identity. Further, applicant's argument that the peptide of SEQ ID No. 2 is naturally occurring and structurally similar supports the possibility of the peptide of SEQ ID No. 1 being naturally expressed but not as yet identified. The claims as written do not distinguish from naturally occurring peptides and are thus drawn to non-statutory subject matter. Amendment of the claims to recite an isolated peptide would obviate this rejection.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

### ***Conclusion***

10. Claims 1, 5, and 7-10 are rejected.

Claims 14, 15, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
March 8, 2010

/Anne M. Gussow/  
Examiner, Art Unit 1643

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643